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*Attorney for Plaintiff
Otsuka Pharmaceutical Co., Ltd.*

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,)
Plaintiff,)
v.)
AMNEAL PHARMACEUTICALS LLC and) Civil Action No.: 15-cv-1585-JBS-KMW
AMNEAL PHARMACEUTICALS INDIA)
PVT. LTD.,)
Defendants.)

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Amneal Pharmaceuticals LLC (“Amneal LLC”) and Amneal Pharmaceuticals India Pvt. Ltd. (“Amneal Ltd.”) (collectively, “Defendants”), alleges as follows:

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Amneal LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

3. Upon information and belief, Amneal Ltd. is a private limited liability company organized and existing under the laws of India, having its principal place of business at 882/1-871, Village: Rajoda, Near Hotel Kankavati, Taluka: Bavla, Ahmedabad-382220, Gujarat, India. Upon information and belief, Amneal Ltd. is a wholly-owned subsidiary of Amneal LLC.

NATURE OF THE ACTION

4. This is an action for infringement of U.S. Patent No. 8,017,615 (“the ’615 patent”), U.S. Patent No. 8,580,796 (“the ’796 patent”), U.S. Patent No. 8,642,760 (“the ’760 patent”) and U.S. Patent No. 8,759,350 (“the ’350 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Amneal LLC’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to manufacture, use, import, sell and offer to sell generic pharmaceutical products (“Defendants’ generic products”) prior to the expiration of the asserted patents, as well as Defendants’ actual manufacture, use, sale, offer for sale and import of Defendants’ generic products upon approval of its ANDA.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has jurisdiction over Amneal LLC. Upon information and belief, Amneal LLC is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal LLC, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Amneal LLC purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district and this judicial district is a likely destination of Defendants' generic products. Upon information and belief, Amneal LLC is registered as a Manufacturer and Wholesaler in the State of New Jersey (No. 5002991) under the trade name "Amneal Pharmaceuticals LLC." See New Jersey Drug Registration and Verification, at <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx> (accessed July 6, 2016). Upon information and belief, Amneal LLC is registered to do business in New Jersey under Business I.D. No. 0600211542. See <http://www.njportal.com/DOR/BusinessNameSearch> (accessed July 6, 2016). Amneal LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction, as well as in this action.

7. This Court has jurisdiction over Amneal Ltd. Upon information and belief, Amneal Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal Ltd., directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Amneal Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction, as well as in this action.

8. Upon information and belief, Amneal LLC and Amneal Ltd. operate as a single integrated business. The Amneal website states that “Amneal sells over 12 billion units of medication annually in the U.S. alone,” and has facilities “both in the U.S. and in India.” *See* <http://amneal.com/operations/>, *see also* <http://amneal.com/operations/manufacturing/>.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

10. The U.S. Patent and Trademark Office (“PTO”) issued the ’615 patent on September 13, 2011, entitled “Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof.” A copy of the ’615 patent is attached as Exhibit A.

11. Otsuka is the owner of the ’615 patent by virtue of assignment.

12. The ’615 patent expires on December 16, 2024 (including pediatric exclusivity).

13. The ’615 patent is directed to and claims, *inter alia*, pharmaceutical solid oral preparations and processes for preparing pharmaceutical solid oral preparations.

14. Otsuka is the holder of New Drug Application (“NDA”) No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.

15. Otsuka lists the ’615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.

16. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.

17. Upon information and belief, Amneal LLC submitted ANDA No. 20-4838 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell Defendants’ generic products in the United States.

18. Otsuka received a letter from Amneal LLC dated January 16, 2015, purporting to include a Notice of Certification for ANDA No. 20-4838 under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and 21 C.F.R. § 314.95(c)(1) (“Amneal LLC’s 20-4838 letter”) as to the ’615 patent.

19. Amneal LLC’s 20-4838 letter alleges that the established name of the drug products that are the subject of Amneal LLC’s ANDA is “Aripiprazole Tablets, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg.”

20. Upon information and belief, Defendants’ generic products will, if approved and marketed, infringe claims 3, 4, 15 and 16 of the ’615 patent.

21. Upon information and belief, Defendants’ generic products are pharmaceutical solid oral preparations containing Anhydrous Aripiprazole Crystals B of low hygroscopicity and one or more pharmaceutically acceptable carriers, as claimed in the ’615 patent.

22. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed claims 3, 4, 15 and 16 of the ’615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4838 seeking approval to manufacture, use, import, offer to sell and sell Defendants’ generic products before the expiration date of the ’615 patent.

23. Upon information and belief, Amneal LLC’s actions relating to Amneal LLC’s ANDA No. 20-4838 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Amneal LLC and Amneal Ltd.

SECOND COUNT FOR PATENT INFRINGEMENT

24. Otsuka realleges, and incorporates in full herein, each preceding paragraph.

25. Amneal LLC’s ANDA No. 20-4838 was approved by the FDA on June 17, 2016.

26. Upon information and belief, Defendants are currently manufacturing, marketing, importing, using, selling and offering for sale Defendants' generic products in connection with ANDA No. 20-4838 throughout the United States.

27. Upon information and belief, Amneal LLC and Amneal Ltd. are infringing claims 3, 4, 15 and 16 of the '615 patent under 35 U.S.C. §§ 271(a)-(c), either directly or indirectly, by the manufacture, market, import, use, sale and offer for sale of Defendants' generic products.

THIRD COUNT FOR PATENT INFRINGEMENT

28. Otsuka realleges, and incorporates in full herein, each preceding paragraph.

29. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

30. Otsuka is the owner of the '796 patent by virtue of assignment.

31. The '796 patent expires on March 25, 2023 (including pediatric exclusivity).

32. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.

33. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

34. Amneal LLC's 20-4838 letter purports to include a Notice of Certification for ANDA No. 20-4838 under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and 21 C.F.R. § 314.95(c)(1) as to the '796 patent.

35. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe claims 1 and 2 of the '796 patent.

36. Upon information and belief, Defendants' generic products contain Anhydrous Aripiprazole Crystals B of low hygroscopicity as claimed in the '796 patent.

37. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed claims 1 and 2 of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4838 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '796 patent.

38. Upon information and belief, Amneal LLC's actions relating to Amneal LLC's ANDA No. 20-4838 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Amneal LLC and Amneal Ltd.

FOURTH COUNT FOR PATENT INFRINGEMENT

39. Otsuka realleges, and incorporates in full herein, each preceding paragraph.

40. Upon information and belief, Amneal LLC and Amneal Ltd. are infringing claims 1 and 2 of the '796 patent under 35 U.S.C. §§ 271(a)-(c) , either directly or indirectly, by the manufacture, market, import, use, sale and offer for sale of Defendants' generic products.

FIFTH COUNT FOR PATENT INFRINGEMENT

41. Otsuka realleges, and incorporates in full herein, each preceding paragraph.

42. The PTO issued the '760 patent on February 4, 2014, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '760 patent is attached as Exhibit C.

43. Otsuka is the owner of the '760 patent by virtue of assignment.

44. The '760 patent expires on March 25, 2023 (including pediatric exclusivity).

45. The '760 patent is directed to and claims, *inter alia*, aripiprazole drug substance.

46. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-436.

47. Amneal LLC's 20-4838 letter purports to include a Notice of Certification for ANDA No. 20-4838 under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and 21 C.F.R. § 314.95(c)(1) as to the '760 patent.

48. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe claims 1 and 2 of the '760 patent.

49. Defendants' generic products contain aripiprazole as the drug substance, as shown in the approved labeling for Defendants' generic products. *See* <http://amneal.com/wp-content/uploads/2016/06/Arripiprazole-Tab-Sol-PI.pdf> (accessed June 29, 2016).

50. Upon information and belief, the aripiprazole drug substance contained in Defendants' generic products is of low hygroscopicity as claimed in the '760 patent.

51. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed claims 1 and 2 of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4838 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '760 patent.

52. Upon information and belief, Amneal LLC's actions relating to Amneal LLC's ANDA No. 20-4838 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Amneal LLC and Amneal Ltd.

SIXTH COUNT FOR PATENT INFRINGEMENT

53. Otsuka realleges, and incorporates in full herein, each preceding paragraph.

54. Upon information and belief, Amneal LLC and Amneal Ltd. are infringing claims 1 and 2 of the '760 patent under 35 U.S.C. §§ 271(a)-(c), either directly or indirectly, by the manufacture, market, import, use, sale and offer for sale of Defendants' generic products.

SEVENTH COUNT FOR PATENT INFRINGEMENT

55. Otsuka realleges, and incorporates in full herein, each preceding paragraph.

56. The U.S. Patent and Trademark Office (“PTO”) issued the ’350 patent on June 24, 2014, entitled “Carbostyryl Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders.” A copy of the ’350 patent is attached as Exhibit D.

57. Otsuka is the owner of the ’350 patent by virtue of assignment.

58. The ’350 patent expires on March 2, 2027, subject to any supplemental patent term adjustment.

59. The ’350 patent is directed to and claims, *inter alia*, pharmaceutical compositions and methods of treatment.

60. Otsuka lists the ’350 patent in the Orange Book for NDA No. 21-436.

61. Amneal LLC’s 20-4838 letter purports to include a Notice of Certification for ANDA No. 20-4838 under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and 21 C.F.R. § 314.95(c)(1) as to the ’350 patent.

62. Upon information and belief, Defendants’ generic products will, if approved and marketed, infringe at least one claim of the ’350 patent.

63. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the ’350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4838 seeking approval to manufacture, use, import, offer to sell and sell Defendants’ generic products before the expiration of the ’350 patent.

64. Upon information and belief, Amneal LLC’s actions relating to Amneal LLC’s ANDA No. 20-4838 complained of herein were done with the cooperation, participation, assistance, and for the benefit of Amneal LLC and Amneal Ltd.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants on the patent infringement claims set forth above and respectfully requests that this Court:

- 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '615 patent through Amneal LLC's submission of ANDA No. 20-4838 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '615 patent;
- 2) order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration of the '615 patent, or such later date as the Court may determine;
- 3) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '615 patent, or such later date as the Court may determine;
- 4) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Amneal LLC's ANDA No. 20-4838 until expiration of the '615 patent;
- 5) enter judgment that, under 35 U.S.C. §§ 271(a)-(c), Defendants have infringed at least one claim of the '615 patent through Defendants' manufacture, market, import, use, sale and offer for sale of Defendants' generic products in the United States before the expiration of the '615 patent;
- 6) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Defendants' infringement of the '615 patent by the

- manufacture, market, import, use, sale and offer for sale of Defendants' generic products, together with interest, in an amount to be determined at trial;
- 7) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '796 patent through Amneal LLC's submission of ANDA No. 20-4838 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '796 patent;
 - 8) order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration of the '796 patent, or such later date as the Court may determine;
 - 9) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '796 patent, or such later date as the Court may determine;
 - 10) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Amneal LLC's ANDA No. 20-4838 until expiration of the '796 patent;
 - 11) enter judgment that, under 35 U.S.C. §§ 271(a)-(c), Defendants have infringed at least one claim of the '796 patent through Defendants' manufacture, market, import, use, sale and offer for sale of Defendants' generic products in the United States before the expiration of the '796 patent;
 - 12) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Defendants' infringement of the '796 patent by the

- manufacture, market, import, use, sale and offer for sale of Defendants' generic products, together with interest, in an amount to be determined at trial;
- 13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '760 patent through Amneal LLC's submission of ANDA No. 20-4838 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '760 patent;
 - 14) order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration of the '760 patent, or such later date as the Court may determine;
 - 15) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '760 patent, or such later date as the Court may determine;
 - 16) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Amneal LLC's ANDA No. 20-4838 until expiration of the '760 patent;
 - 17) enter judgment that, under 35 U.S.C. §§ 271(a)-(c), Defendants have infringed at least one claim of the '760 patent through Defendants' manufacture, market, import, use, sale and offer for sale of Defendants' generic products in the United States before the expiration of the '760 patent;
 - 18) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Defendants' infringement of the '760 patent by the

- manufacture, market, import, use, sale and offer for sale of Defendants' generic products, together with interest, in an amount to be determined at trial;
- 19) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '350 patent through Amneal LLC's submission of ANDA No. 20-4838 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '350 patent;
 - 20) order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration of the '350 patent, or such later date as the Court may determine;
 - 21) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '350 patent, or such later date as the Court may determine;
 - 22) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Amneal LLC's ANDA No. 20-4838 until expiration of the '350 patent;
 - 23) find Defendants' infringement to have been willful and award Otsuka enhanced damages for this willful infringement;
 - 24) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and
 - 25) award Otsuka such further and additional relief as this Court deems just and proper.

Date: July 18, 2016

Respectfully submitted,

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